

CHRISTIE PABARUE and YOUNG,
A Professional Corporation
1880 JFK Boulevard 10th Floor
Philadelphia, Pennsylvania 19103
(215) 587-1678; jwchristie@cpmy.com

Attorney of Record: James W. Christie, Esq.
Attorney for Defendants

Of Counsel

Enu Mainigi, Esq. (*pro hac vice*)
Jennifer G. Wicht, Esq. (*pro hac vice*)
WILLIAMS & CONNOLLY LLP
725 Twelfth Street, Northwest
Washington, District of Columbia 20005
(202) 434-5000; emainigi@wc.com, jwicht@wc.com

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

UNITED STATES OF AMERICA
ex. rel. STEVE GREENFIELD, et al.,

Plaintiff,

V.

**MEDCO HEALTH SYSTEMS, INC.,
ACCREDITO HEALTH GROUP, INC.,
and HEMOPHILIA HEALTH
SERVICES, INC.,**

Defendants.

Civil No. 1:12-cv-00522-NLH-AMD

DEFENDANTS' ANSWER AND DEMAND FOR JURY TRIAL

Medco Health Solutions, Inc. (incorrectly sued as Medco Health Systems, Inc.) (“Medco”), Accredo Health Group, Inc. (“Accredo”), and Hemophilia Health

Services, Inc.¹ (“HHS”) (collectively, “Defendants”), by and through their undersigned attorneys, hereby answer Relator’s Fourth Amended Qui Tam Complaint (“FAC”) and assert affirmative defenses.

1. Defendants admit that Relator purports to bring a civil action pursuant to 31 U.S.C. §§ 3729 and 3730. The remainder of Paragraph 1 of the FAC asserts a legal conclusion to which no response is required. To the extent that any further response is required, Defendants deny the allegations contained in Paragraph 1 of the FAC.

2. Defendants deny the allegations contained in Paragraph 2 of the FAC, except Defendants admit that Medco Health Solutions, Inc. (incorrectly sued as Medco Health Systems, Inc.) is a health care company that provides, inter alia, pharmacy benefit management services, and that Accredo provides specialty pharmacy and related services for patients with certain complex and chronic conditions. Defendants further state that HHS was merged into Accredo effective January 1, 2006.

3. Paragraph 3 of the FAC asserts a legal conclusion to which no response is required. To the extent that any further response is required, Defendants deny the allegations contained in Paragraph 3 of the FAC. Defendants further state that HHS was merged into Accredo effective January 1, 2006.

¹ HHS was merged into Accredo effective January 1, 2006.

4. Defendants deny the allegations contained in Paragraph 4 of the FAC.

5. Defendants deny the allegations contained in Paragraph 5 of the FAC, except Defendants admit upon information and belief that Hemophilia Services, Inc. (“HSI”) and Hemophilia Association of New Jersey (“HANJ”) are 501(c)(3) charitable organizations.

6. Defendants lack knowledge or information sufficient to admit or deny the allegations contained in Paragraph 6 of the FAC and, on that basis, deny the allegations, except Defendants admit upon information and belief that HANJ, among other activities, may make grants to hemophilia treatment centers (HTCs) and that New Jersey regulatory authorities, pursuant to statute and/or regulation, may receive recommendations from HANJ with respect to providers of hemophilia products and services.

7. Defendants deny the allegations contained in Paragraph 7 of the FAC.

8. Defendants deny the allegations contained in Paragraph 8 of the FAC.

9. Defendants deny the allegations contained in Paragraph 9 of the FAC.

Defendants further state that HHS was merged into Accredo effective January 1, 2006.

10. Sentences one and two of Paragraph 10 of the FAC purport to quote from, characterize, or describe a statutory and regulatory regime, the underlying

statutes and regulations of which are the best record of its contents. To the extent any further response is required, Defendants deny the allegations contained in sentences one and two of Paragraph 10 of the FAC to the extent they are inconsistent with the underlying statutes or regulations. Defendants deny the allegations contained in sentences three and four of Paragraph 10 of the FAC.

11. Defendants deny the allegations contained in Paragraph 11 of the FAC, except Defendants admit that the hemophilia-affected population is small relative to some other populations affected by chronic medical conditions, and that medications to treat hemophilia can be expensive relative to some other medications.

12. Defendants lack knowledge or information sufficient to admit or deny the allegations contained in Paragraph 12 of the FAC and, on that basis, deny the allegations.

13. Defendants lack knowledge or information sufficient to admit or deny the allegations contained in Paragraph 13 of the FAC and, on that basis, deny the allegations.

14. Defendants lack knowledge or information sufficient to admit or deny the allegations contained in Paragraph 14 of the FAC and, on that basis, deny the allegations, except Defendants admit that Relator was employed as an Area Vice

President for Accredo from on or about November 9, 2009 until his employment was terminated effective on or about February 1, 2012.

15. Defendants deny the allegations contained in Paragraph 15 of the FAC.

16. Defendants admit that Medco is a Delaware corporation with its principal office located at 100 Parsons Pond Drive, Franklin Lakes, NJ 07417-2603, and that Medco is a pharmacy benefit management company with clients that include private and public employers, health plans, labor unions and government agencies of various sizes and entities offering Medicare Part D prescription drug plans. Defendants deny the remaining allegations contained in Paragraph 16 of the FAC.

17. Defendants deny the allegations contained in Paragraph 17, except Defendants admit that Medco holds contracts with payors, retail pharmacies, dispensing physicians and some pharmaceutical manufacturers.

18. Defendants admit that Accredo is headquartered in Memphis, Tennessee, that it provides specialty pharmacy and related services for patients with certain complex and chronic conditions, that it is a wholly owned subsidiary of Medco Health Solutions, Inc., that it is one of the largest specialty pharmacy providers based on reported revenues, and that specialty medications are generally manufactured by biopharmaceutical or biotechnology companies and tend to be

more expensive than traditional medicines and can cost as much as several hundred thousand dollars per patient per year. Defendants deny the remaining allegations contained in Paragraph 18 of the FAC.

19. Defendants admit the allegations contained in Paragraph 19 of the FAC, except Defendants further state that Accredo also focuses on infused and inhaled drugs.

20. Defendants admit the allegations contained in sentences one through four of Paragraph 20 of the FAC. Defendants further state that patients receive counseling and education services that include, but are not limited to, training on how to self-administer specialty medications, advice on how to cope with potential side-effects, and access to clinical resources that are available around the clock to assist patients in managing critical aspects of care. Defendants deny the remaining allegations contained in Paragraph 20 of the FAC.

21. Defendants admit the allegations contained in Paragraph 21 of the FAC.

22. Defendants deny the allegations contained in Paragraph 22, except Defendants admit that Accredo's Therapeutic Resource Centers are segmented by therapy and Accredo supports therapy management for patients with rheumatoid arthritis, multiple sclerosis, cancer, hepatitis C, immune disorders, pulmonary arterial hypertension and hemophilia, among other conditions.

23. Defendants deny the allegations contained in sentence one of Paragraph 23 of the FAC, except Defendants admit that Craig Mears was President of HHS. Defendants deny the allegations contained in sentence two of Paragraph 23 of the FAC. Defendants lack knowledge or information sufficient to admit or deny the allegations contained in sentence three of Paragraph 23 of the FAC and, on that basis, deny the allegations. Defendants deny the allegations contained in sentences four and five of Paragraph 23 of the FAC. Defendants further state that HHS was merged into Accredo effective January 1, 2006.

24. Paragraph 24 of the FAC purports to quote from, characterize, or describe documents, which documents are the best record of their contents. To the extent any further response is required, Defendants deny the allegations contained in Paragraph 24 of the FAC to the extent they are inconsistent with the documents.

25. Defendants deny the allegations contained in Paragraph 25 of the FAC, except Defendants admit that HHS was founded in 1990 and was based in Nashville, Tennessee. Defendants further state that HHS was merged into Accredo effective January 1, 2006.

26. Defendants lack knowledge or information sufficient to admit or deny the allegations contained in Paragraph 26 of the FAC and, on that basis, deny the allegations, except Defendants admit upon information and belief that HANJ is a 501(c)(3) charitable organization, that HANJ offers assistance to persons with

hemophilia and their families, that HANJ (among other activities) may make grants to hemophilia treatment centers (HTCs), and that New Jersey regulatory authorities, pursuant to statute and/or regulation, may receive recommendations from HANJ with respect to providers of hemophilia products and services.

27. Paragraph 27 of the FAC purports to quote from, characterize, or describe documents, which documents are the best record of their contents. To the extent any further response is required, Defendants deny the allegations contained in Paragraph 27 of the FAC to the extent they are inconsistent with the documents. Defendants lack knowledge or information sufficient to admit or deny the contents of the documents themselves.

28. Defendants lack knowledge or information sufficient to admit or deny the allegations contained in Paragraph 28 of the FAC and, on that basis, deny the allegations, except Defendants admit upon information and belief that HSI is a 501(c)(3) organization and may (among other activities) provide case management services for certain hemophilia-affected patients in New Jersey.

29. Defendants lack knowledge or information sufficient to admit or deny the allegations contained in Paragraph 29 of the FAC and, on that basis, deny the allegations.

30. Paragraph 30 of the FAC asserts a legal conclusion to which no response is required. To the extent that any further response is required, Defendants deny the allegations contained in Paragraph 30 of the FAC.

31. Defendants admit that the Centers for Medicare & Medicaid Services (CMS), of the U.S. Department of Health and Human Services (HHS), has administrative responsibilities with respect to the Medicare program. The remainder of Paragraph 31 of the FAC asserts legal conclusions to which no response is required. To the extent that any further response is required, Defendants deny the allegations contained in Paragraph 31 of the FAC.

32. Paragraph 32 of the FAC asserts a legal conclusion to which no response is required. To the extent any further response is required, Defendants deny the allegations contained in Paragraph 32 of the FAC.

33. Paragraph 33 of the FAC asserts a legal conclusion to which no response is required. To the extent any further response is required, Defendants deny the allegations contained in Paragraph 33 of the FAC, except Defendants admit that Relator's state-law claims were dismissed by the Court.

34. Paragraph 34 of the FAC asserts a legal conclusion to which no response is required. To the extent any further response is required, Defendants deny the allegations contained in Paragraph 34 of the FAC, except Defendants

admit that one or more of the Defendants transacts some business in the District of New Jersey.

35. Paragraph 35 of the FAC purports to quote from, characterize, or describe a statutory and regulatory regime, the underlying statutes and regulations of which are the best record of its contents. To the extent any further response is required, Defendants deny the allegations contained in Paragraph 35 of the FAC to the extent they are inconsistent with the underlying statutes or regulations.

36. Paragraph 36 of the FAC purports to quote from, characterize, or describe a statutory and regulatory regime, the underlying statutes and regulations of which are the best record of its contents. To the extent any further response is required, Defendants deny the allegations contained in Paragraph 36 of the FAC to the extent they are inconsistent with the underlying statutes or regulations.

37. Paragraph 37 of the FAC purports to quote from, characterize, or describe a statutory and regulatory regime, the underlying statutes and regulations of which are the best record of its contents. To the extent any further response is required, Defendants deny the allegations contained in Paragraph 37 of the FAC to the extent they are inconsistent with the underlying statutes or regulations.

38. Defendants lack knowledge or information sufficient to admit or deny the allegations contained in Paragraph 38 of the FAC and, on that basis, deny the allegations, except Defendants admit that some components of the federal

government are provider(s) and/or purchaser(s) of health care services, including prescription drugs.

39. Defendants admit the allegations contained in Paragraph 39 of the FAC, except Defendants deny that the Federal Employees Health Benefits Program is a Federal Health Care Program or a Government Health Care Program for purposes of liability under the False Claims Act and Anti-Kickback Statute.

40. Paragraph 40 of the FAC purports to quote from, characterize, or describe a statutory and regulatory regime, the underlying statutes and regulations of which are the best record of its contents. To the extent any further response is required, Defendants deny the allegations contained in Paragraph 40 of the FAC to the extent they are inconsistent with the underlying statutes or regulations.

41. Paragraph 41 of the FAC purports to quote from, characterize, or describe a statutory and regulatory regime, the underlying statutes and regulations of which are the best record of its contents. To the extent any further response is required, Defendants deny the allegations contained in Paragraph 41 of the FAC to the extent they are inconsistent with the underlying statutes or regulations.

42. Paragraph 42 of the FAC purports to quote from, characterize, or describe a statutory and regulatory regime, the underlying statutes and regulations of which are the best record of its contents. To the extent any further response is

required, Defendants deny the allegations contained in Paragraph 42 of the FAC to the extent they are inconsistent with the underlying statutes or regulations.

43. Paragraph 43 of the FAC purports to quote from, characterize, or describe a statutory and regulatory regime, the underlying statutes and regulations of which are the best record of its contents. To the extent any further response is required, Defendants deny the allegations contained in Paragraph 43 of the FAC to the extent they are inconsistent with the underlying statutes or regulations. The last sentence of Paragraph 43 of the FAC asserts a legal conclusion to which no response is required. To the extent any further response is required, Defendants deny the allegations contained in the last sentence of Paragraph 43.

44. Paragraph 44 of the FAC purports to quote from, characterize, or describe documents, which documents are the best record of their contents. To the extent any further response is required, Defendants deny the allegations contained in Paragraph 44 of the FAC to the extent they are inconsistent with the documents.

45. Paragraph 45 of the FAC purports to quote from, characterize, or describe documents, which documents are the best record of their contents. To the extent any further response is required, Defendants deny the allegations contained in Paragraph 45 of the FAC to the extent they are inconsistent with the documents.

46. Defendants admit the allegations contained in Paragraph 46 of the FAC.

47. Defendants admit the allegations contained in Paragraph 47 of the FAC.

48. Defendants admit the allegations contained in Paragraph 48 of the FAC.

49. Defendants admit the allegations contained in Paragraph 49 of the FAC.

50. Defendants admit the allegations contained in Paragraph 50 of the FAC.

51. Defendants admit the allegations contained in Paragraph 51 of the FAC, except Defendants further state that the amount of factor needed is based on both the severity of the bleed and the patient's weight.

52. Defendants admit the allegations contained in Paragraph 52 of the FAC, except Defendants further state that treating a bleed when it starts with infusions of clotting factor may also be referred to as episodic therapy.

53. Defendants admit the allegations contained in Paragraph 53 of the FAC.

54. Defendants admit the allegations contained in Paragraph 54 of the FAC, except Defendants deny that HHS acts as a Specialty Pharmacy Provider, and Defendants further state that XYNTHA may also be available in measurements

of 250 IU, 500 IU, 1,000 IU, and 2,000 IU. Defendants further state that HHS was merged into Accredo effective January 1, 2006.

55. Paragraph 55 of the FAC purports to quote from, characterize, or describe a statutory and regulatory regime, the underlying statutes and regulations of which are the best record of its contents. To the extent any further response is required, Defendants deny the allegations contained in Paragraph 55 of the FAC to the extent they are inconsistent with the underlying statutes or regulations.

56. Paragraph 56 of the FAC purports to quote from, characterize, or describe a statutory and regulatory regime, the underlying statutes and regulations of which are the best record of its contents. To the extent any further response is required, Defendants deny the allegations contained in Paragraph 56 of the FAC to the extent they are inconsistent with the underlying statutes or regulations.

57. Defendants lack knowledge or information sufficient to admit or deny the allegations contained in Paragraph 57 of the FAC and, on that basis, deny the allegations, except Defendants admit Accredo and, upon information and belief, the other three named companies, have provided hemophilia products or services.

58. Defendants lack knowledge or information sufficient to admit or deny the allegations contained in sentences one and two of Paragraph 58 of the FAC and, on that basis, deny the allegations. Sentences three through ten of Paragraph 58 of the FAC purport to quote from, characterize, or describe a statutory and

regulatory regime, the underlying statutes and regulations of which are the best record of its contents. To the extent any further response is required, Defendants deny the allegations contained in sentences three through ten of Paragraph 58 of the FAC to the extent they are inconsistent with the underlying statutes or regulations.

59. Paragraph 59 of the FAC purports to quote from, characterize, or describe a statutory and regulatory regime, the underlying statutes and regulations of which are the best record of its contents. To the extent any further response is required, Defendants deny the allegations contained in Paragraph 59 of the FAC to the extent they are inconsistent with the underlying statutes or regulations.

60. Paragraph 60 of the FAC purports to quote from, characterize, or describe a statutory and regulatory regime, the underlying statutes and regulations of which are the best record of its contents. To the extent any further response is required, Defendants deny the allegations contained in Paragraph 60 of the FAC to the extent they are inconsistent with the underlying statutes or regulations.

61. Sentences one and two of Paragraph 61 of the FAC purport to quote from, characterize, or describe a statutory and regulatory regime, the underlying statutes and regulations of which are the best record of its contents. To the extent any further response is required, Defendants deny the allegations contained in sentences one and two of Paragraph 61 of the FAC to the extent they are

inconsistent with the underlying statutes or regulations. Defendants lack knowledge or information sufficient to admit or deny the allegations contained in sentence three of Paragraph 61 of the FAC and, on that basis, deny the allegations.

62. Defendants lack knowledge or information sufficient to admit or deny the allegations contained in sentences one through three of Paragraph 62 of the FAC and, on that basis, deny the allegations. Sentences four through six of Paragraph 62 of the FAC purport to quote from, characterize, or describe documents, which documents are the best record of their contents. To the extent any further response is required, Defendants deny the allegations contained in sentences four through six of Paragraph 62 of the FAC to the extent they are inconsistent with the documents. Defendants presently lack knowledge or information sufficient to admit or deny the contents of the documents themselves. Defendants further state that HHS was merged into Accredo effective January 1, 2006.

63. Paragraph 63 of the FAC purports to quote from, characterize, or describe documents, which documents are the best record of their contents. To the extent any further response is required, Defendants deny the allegations contained in Paragraph 63 of the FAC to the extent they are inconsistent with the documents. Defendants lack knowledge or information sufficient to admit or deny the contents of the documents themselves.

64. Defendants deny the allegations contained in Paragraph 64 of the FAC, except Defendants admit that Medicare Part B coverage may be available for outpatient prescription drugs and biologicals that are not usually self-administered and are provided pursuant to a physician's services.

65. Paragraph 65 of the FAC purports to quote from, characterize, or describe documents, which documents are the best record of their contents. To the extent any further response is required, Defendants deny the allegations contained in Paragraph 65 of the FAC to the extent they are inconsistent with the documents. Defendants lack knowledge or information sufficient to admit or deny the contents of the documents themselves.

66. Defendants deny the allegations contained in Paragraph 66 of the FAC.

67. Defendants deny the allegations contained in sentence one of Paragraph 67 of the FAC. Sentences two and three of Paragraph 67 of the FAC purport to quote from, characterize, or describe documents, which documents are the best record of their contents. To the extent any further response is required, Defendants deny the allegations contained in sentences two and three of Paragraph 67 of the FAC to the extent they are inconsistent with the documents. Defendants presently lack knowledge or information sufficient to admit or deny the contents of

the documents themselves. Defendants further state that HHS was merged into Accredo effective January 1, 2006.

68. Defendants lack knowledge or information sufficient to admit or deny the allegations contained in sentence one of Paragraph 68 of the FAC and, on that basis, deny the allegations. Defendants deny the allegations contained in sentence two of Paragraph 68 of the FAC.

69. Defendants deny the allegations contained in sentence one of Paragraph 69 of the FAC, except Defendants admit upon information and belief that HANJ is a non-profit support group for hemophilia patients in New Jersey. Sentences two and three of Paragraph 69 of the FAC purport to quote from, characterize, or describe documents, which documents are the best record of their contents. To the extent any further response is required, Defendants deny the allegations contained in sentences two and three of Paragraph 69 of the FAC to the extent they are inconsistent with the documents. Defendants lack knowledge or information sufficient to admit or deny the contents of the documents themselves. Defendants lack knowledge or information sufficient to admit or deny the allegations contained in sentence four of Paragraph 69 of the FAC and, on that basis, deny the allegations.

70. Paragraph 70 of the FAC purports to quote from, characterize, or describe documents, which documents are the best record of their contents. To the

extent any further response is required, Defendants deny the allegations contained in Paragraph 70 of the FAC to the extent they are inconsistent with the documents. Defendants lack knowledge or information sufficient to admit or deny the contents of the documents themselves.

71. Paragraph 71 of the FAC purports to quote from, characterize, or describe documents, which documents are the best record of their contents. To the extent any further response is required, Defendants deny the allegations contained in Paragraph 71 of the FAC to the extent they are inconsistent with the documents. Defendants lack knowledge or information sufficient to admit or deny the contents of the documents themselves.

72. Paragraph 72 of the FAC purports to quote from, characterize, or describe documents, which documents are the best record of their contents. To the extent any further response is required, Defendants deny the allegations contained in Paragraph 72 of the FAC to the extent they are inconsistent with the documents. Defendants lack knowledge or information sufficient to admit or deny the contents of the documents themselves.

73. Paragraph 73 of the FAC purports to quote from, characterize, or describe documents, which documents are the best record of their contents. To the extent any further response is required, Defendants deny the allegations contained in Paragraph 73 of the FAC to the extent they are inconsistent with the documents.

Defendants lack knowledge or information sufficient to admit or deny the contents of the documents themselves.

74. Defendants lack knowledge or information sufficient to admit or deny the allegations contained in Paragraph 74 of the FAC and, on that basis, deny the allegations. To the extent Paragraph 74 of the FAC purports to quote from, characterize, or describe documents, those documents are the best record of their contents. To the extent any further response is required, Defendants deny the allegations contained in Paragraph 74 of the FAC to the extent they are inconsistent with the documents. Defendants presently lack knowledge or information sufficient to admit or deny the contents of the documents themselves. Defendants further state that HHS was merged into Accredo effective January 1, 2006.

75. Defendants deny the allegations contained in Paragraph 75 of the FAC, except that Defendants admit that various employees of Accredo at times communicated amongst themselves and with employees and/or board members of HANJ and/or HSI regarding charitable contributions. Defendants further state that HHS was merged into Accredo effective January 1, 2006.

76. Defendants deny the allegations contained in sentence one of Paragraph 76 of the FAC. Defendants lack knowledge or information sufficient to admit or deny the allegations contained in the remainder of Paragraph 76 of the

FAC and, on that basis, deny the allegations. To the extent Paragraph 76 of the FAC purports to quote from, characterize, or describe documents, those documents are the best record of their contents. To the extent any further response is required, Defendants deny the allegations contained in Paragraph 76 of the FAC to the extent they are inconsistent with the documents. Defendants presently lack knowledge or information sufficient to admit or deny the contents of the documents themselves.

77. Paragraph 77 of the FAC purports to quote from, characterize, or describe documents, which documents are the best record of their contents. To the extent any further response is required, Defendants deny the allegations contained in Paragraph 77 of the FAC to the extent they are inconsistent with the documents. Defendants presently lack knowledge or information sufficient to admit or deny the contents of the documents themselves. Defendants further state that HHS was merged into Accredo effective January 1, 2006.

78. Paragraph 78 of the FAC purports to quote from, characterize, or describe documents, which documents are the best record of their contents. To the extent any further response is required, Defendants deny the allegations contained in Paragraph 78 of the FAC to the extent they are inconsistent with the documents. Defendants presently lack knowledge or information sufficient to admit or deny the contents of the documents themselves. Defendants deny that Craig Mears was

President of Accredo. Defendants further state that HHS was merged into Accredo effective January 1, 2006.

79. Paragraph 79 of the FAC purports to quote from, characterize, or describe documents, which documents are the best record of their contents. To the extent any further response is required, Defendants deny the allegations contained in Paragraph 79 of the FAC to the extent they are inconsistent with the documents. Defendants presently lack knowledge or information sufficient to admit or deny the contents of the documents themselves. Footnote 36 of Paragraph 79 purports to quote from, characterize, or describe a statutory and regulatory regime, the underlying statutes and regulations of which are the best record of its contents. To the extent any further response is required, Defendants deny the allegations contained in Footnote 36 of Paragraph 79 of the FAC to the extent they are inconsistent with the underlying statutes or regulations. Defendants further state that HHS was merged into Accredo effective January 1, 2006.

80. Paragraph 80 of the FAC purports to quote from, characterize, or describe documents, which documents are the best record of their contents. To the extent any further response is required, Defendants deny the allegations contained in Paragraph 80 of the FAC to the extent they are inconsistent with the documents. Defendants presently lack knowledge or information sufficient to admit or deny the

contents of the documents themselves. Defendants further state that HHS was merged into Accredo effective January 1, 2006.

81. Defendants lack knowledge or information sufficient to admit or deny the allegations contained in sentence one of Paragraph 81 of the FAC and, on that basis, deny the allegations. Sentences two and three of Paragraph 81 of the FAC purport to quote from, characterize, or describe documents, which documents are the best record of their contents. To the extent any further response is required, Defendants deny the allegations contained in sentences two and three of Paragraph 81 of the FAC to the extent they are inconsistent with the documents. Defendants presently lack knowledge or information sufficient to admit or deny the contents of the documents themselves. Defendants lack knowledge or information sufficient to admit or deny the allegations contained in sentence four of Paragraph 81 of the FAC and, on that basis, deny the allegations. Defendants further state that HHS was merged into Accredo effective January 1, 2006.

82. Paragraph 82 of the FAC purports to quote from, characterize, or describe documents, which documents are the best record of their contents. To the extent any further response is required, Defendants deny the allegations contained in Paragraph 82 of the FAC to the extent they are inconsistent with the documents. Defendants presently lack knowledge or information sufficient to admit or deny the contents of the documents themselves.

83. Defendants lack knowledge or information sufficient to admit or deny the allegations contained in Paragraph 83 of the FAC and, on that basis, deny the allegations. Defendants further state that HHS was merged into Accredo effective January 1, 2006.

84. Defendants lack knowledge or information sufficient to admit or deny the allegations contained in Paragraph 84 of the FAC and, on that basis, deny the allegations. Defendants further state that HHS was merged into Accredo effective January 1, 2006.

85. Defendants lack knowledge or information sufficient to admit or deny the allegations contained in sentences one and two of Paragraph 85 of the FAC and, on that basis, deny the allegations. Defendants deny the allegations contained in sentence three of Paragraph 85 of the FAC.

86. Defendants lack knowledge or information sufficient to admit or deny the allegations contained in Paragraph 86 of the FAC and, on that basis, deny the allegations.

87. Defendants lack knowledge or information sufficient to admit or deny the allegations contained in Paragraph 87 of the FAC and, on that basis, deny the allegations.

88. Defendants lack knowledge or information sufficient to admit or deny the allegations contained in sentence one of Paragraph 88 of the FAC and, on that

basis, deny the allegations. The remainder of Paragraph 88 of the FAC purports to quote from, characterize, or describe documents, which documents are the best record of their contents. To the extent any further response is required, Defendants deny the allegations contained in the remainder of Paragraph 88 of the FAC to the extent they are inconsistent with the documents. Defendants lack knowledge or information sufficient to admit or deny the contents of the documents themselves. Defendants further state that HHS was merged into Accredo effective January 1, 2006.

89. Defendants admit that Accredo received, in or around March of 2011, correspondence addressed to Craig Mears and purporting to be from members of HANJ and/or HSI. Sentences two through five of Paragraph 89 of the FAC purport to quote from, characterize, or describe documents, which documents are the best record of their contents. To the extent any further response is required, Defendants deny the allegations contained in sentences two through five of Paragraph 89 of the FAC to the extent they are inconsistent with the documents. Defendants lack knowledge or information sufficient to admit or deny the contents of the documents themselves. Defendants lack knowledge or information sufficient to admit or deny the allegations contained in sentence six of Paragraph 89 of the FAC and, on that basis, deny the allegations. Defendants further state that HHS was merged into Accredo effective January 1, 2006.

90. Defendants deny the allegations contained in sentence one of Paragraph 90 of the FAC. Sentences two through four of Paragraph 90 of the FAC purport to quote from, characterize, or describe documents, which documents are the best record of their contents. To the extent any further response is required, Defendants deny the allegations contained in sentences two through four of Paragraph 89 of the FAC to the extent they are inconsistent with the documents. Defendants presently lack knowledge or information sufficient to admit or deny the contents of the documents themselves. Defendants further state that HHS was merged into Accredo effective January 1, 2006.

91. Paragraph 91 of the FAC purports to quote from, characterize, or describe documents, which documents are the best record of their contents. To the extent any further response is required, Defendants deny the allegations contained in Paragraph 91 of the FAC to the extent they are inconsistent with the documents. Defendants presently lack knowledge or information sufficient to admit or deny the contents of the documents themselves. Defendants deny that Craig Mears was President of Accredo.

92. Paragraph 92 of the FAC purports to quote from, characterize, or describe documents, which documents are the best record of their contents. To the extent any further response is required, Defendants deny the allegations contained in Paragraph 92 of the FAC to the extent they are inconsistent with the documents.

Defendants presently lack knowledge or information sufficient to admit or deny the contents of the documents themselves. Defendants further state that HHS was merged into Accredo effective January 1, 2006.

93. Paragraph 93 of the FAC purports to quote from, characterize, or describe documents, which documents are the best record of their contents. To the extent any further response is required, Defendants deny the allegations contained in Paragraph 93 of the FAC to the extent they are inconsistent with the documents. Defendants presently lack knowledge or information sufficient to admit or deny the contents of the documents themselves.

94. Defendants lack knowledge or information sufficient to admit or deny the allegations contained in Paragraph 94 of the FAC and, on that basis, deny the allegations. Defendants deny that Craig Mears was President of Accredo. Further, portions of Paragraph 94 of the FAC purport to quote from, characterize, or describe documents, which documents are the best record of their contents. To the extent any further response is required, Defendants deny the allegations contained in Paragraph 94 of the FAC to the extent they are inconsistent with the documents. Defendants deny that Relator's notes reflect a comprehensive or accurate portrayal of any alleged discussions. Defendants further state that HHS was merged into Accredo effective January 1, 2006.

95. Paragraph 95 of the FAC purports to quote from, characterize, or describe documents, which documents are the best record of their contents. To the extent any further response is required, Defendants deny the allegations contained in Paragraph 95 of the FAC to the extent they are inconsistent with the documents. Defendants deny that Relator's notes reflect a comprehensive or accurate portrayal of any alleged discussions.

96. Defendants deny the allegations contained in sentence one of Paragraph 96 of the FAC. The remainder of Paragraph 96 of the FAC purports to quote from, characterize, or describe documents, which documents are the best record of their contents. To the extent any further response is required, Defendants deny the allegations contained in the remainder of Paragraph 96 of the FAC to the extent they are inconsistent with the documents. Defendants deny that Relator's notes reflect a comprehensive or accurate portrayal of any alleged discussions.

97. Defendants deny the allegations contained in Paragraph 97 of the FAC.

98. Sentences one through four of Paragraph 98 of the FAC purport to quote from, characterize, or describe documents, which documents are the best record of their contents. To the extent any further response is required, Defendants deny the allegations contained in sentences one through four of Paragraph 98 of the

FAC to the extent they are inconsistent with the documents. Defendants deny the allegations contained in sentences five and six of Paragraph 98 of the FAC.

99. Sentences one and two of Paragraph 99 of the FAC purport to quote from, characterize, or describe documents, which documents are the best record of their contents. To the extent any further response is required, Defendants deny the allegations contained in sentences one and two of Paragraph 99 of the FAC to the extent they are inconsistent with the documents. Defendants deny the allegations contained in sentences three through six of Paragraph 99 of the FAC.

100. Sentences one through four of Paragraph 100 of the FAC purport to quote from, characterize, or describe documents, which documents are the best record of their contents. To the extent any further response is required, Defendants deny the allegations contained in sentences one through four of Paragraph 100 of the FAC to the extent they are inconsistent with the documents. Defendants deny the allegations contained in sentences five through eleven of paragraph 100 of the FAC.

101. Sentences one and two of Paragraph 101 of the FAC purport to quote from, characterize, or describe documents, which documents are the best record of their contents. To the extent any further response is required, Defendants deny the allegations contained in sentences one and two of Paragraph 101 of the FAC to the

extent they are inconsistent with the documents. Defendants deny the allegations contained in sentences three through five of Paragraph 101 of the FAC.

102. Sentences one through four of Paragraph 102 of the FAC purport to quote from, characterize, or describe documents, which documents are the best record of their contents. To the extent any further response is required, Defendants deny the allegations contained in sentences one through four of Paragraph 102 of the FAC to the extent they are inconsistent with the documents. Defendants deny the allegations contained in sentences five through seven of Paragraph 102 of the FAC.

103. Paragraph 103 of the FAC asserts a legal conclusion to which no response is required. To the extent that any further response is required, Defendants deny the allegations contained in Paragraph 103 of the FAC.

104. Defendants admit that Baxter is a manufacturer of factor and supplier to Accredo. Defendants lack knowledge or information sufficient to admit or deny the remaining allegations contained in Paragraph 104 of the FAC and, on that basis, deny the allegations.

105. Defendants admit that Accredo purchases factor from a number of different suppliers. The remainder of Paragraph 105 of the FAC purports to quote from, characterize, or describe documents, which documents are the best record of their contents. To the extent any further response is required, Defendants deny the

remaining allegations contained in Paragraph 105 of the FAC to the extent they are inconsistent with the documents. Defendants lack knowledge or information sufficient to admit or deny the contents of the documents themselves.

106. Defendants lack knowledge or information sufficient to admit or deny the allegations contained in Paragraph 106 of the FAC and, on that basis, deny the allegations.

107. Sentences one and two of Paragraph 107 of the FAC purport to quote from, characterize, or describe documents, which documents are the best record of their contents. To the extent any further response is required, Defendants deny the allegations contained in sentences one and two of Paragraph 107 of the FAC to the extent they are inconsistent with the documents. Defendants presently lack knowledge or information sufficient to admit or deny the contents of the documents themselves. Footnote 46 to Paragraph 107 of the FAC purports to quote from, characterize, or describe a statutory and regulatory regime, the underlying statutes and regulations of which are the best record of its contents. To the extent any further response is required, Defendants deny the allegations contained in footnote 46 to Paragraph 107 of the FAC to the extent they are inconsistent with the underlying statutes or regulations. Defendants deny the allegations contained in sentence three of Paragraph 107 of the FAC.

108. Defendants deny the allegations contained in sentence one of Paragraph 108 of the FAC. Sentence two of Paragraph 108 of the FAC purports to quote from, characterize, or describe documents, which documents are the best record of their contents. To the extent any further response is required, Defendants deny the allegations contained in sentence two of Paragraph 108 of the FAC to the extent they are inconsistent with the documents. Defendants presently lack knowledge or information sufficient to admit or deny the contents of the documents themselves. Defendants further state that HHS was merged into Accredo effective January 1, 2006.

109. Defendants admit that Accredo has executed one or more provider agreements on CMS Form 855S. The remainder of Paragraph 109 of the FAC purports to quote from, characterize, or describe documents, which documents are the best record of their contents. To the extent any further response is required, Defendants deny the allegations contained in the remainder of Paragraph 109 of the FAC to the extent they are inconsistent with the documents.

110. Defendants deny the allegations contained in sentence one of Paragraph 110 of the FAC. The remainder of Paragraph 110 of the FAC purports to quote from, characterize, or describe documents, which documents are the best record of their contents. To the extent any further response is required, Defendants

deny the allegations contained in the remainder of Paragraph 110 of the FAC to the extent they are inconsistent with the documents.

111. Defendants deny the allegations contained in Paragraph 111 of the FAC.

112. Paragraph 112 of the FAC asserts legal conclusions to which no response is required. To the extent that any further response is required, Defendants deny the allegations contained in Paragraph 112 of the FAC.

113. Defendants deny the allegations contained in Paragraph 113 of the FAC, except Defendants admit that the hemophilia-affected population is small relative to some other populations affected by chronic medical conditions, and that medications to treat hemophilia can be expensive relative to some other medications.

114. Paragraph 114 of the FAC asserts legal conclusions to which no response is required. To the extent that any further response is required, Defendants deny the allegations contained in Paragraph 114 of the FAC.

115. Paragraph 115 of the FAC asserts legal conclusions to which no response is required. To the extent that any further response is required, Defendants deny the allegations contained in Paragraph 115 of the FAC.

116. Defendants admit that Accredo has executed one or more provider agreements on CMS Form 855S. The remainder of Paragraph 116 of the FAC

purports to quote from, characterize, or describe documents, which documents are the best record of their contents. To the extent any further response is required, Defendants deny the allegations contained in the remainder of Paragraph 116 of the FAC to the extent they are inconsistent with the documents.

117. Paragraph 117 of the FAC asserts legal conclusions to which no response is required. To the extent that any further response is required, Defendants deny the allegations contained in Paragraph 117 of the FAC.

118. Defendants incorporate by reference their responses to all allegations set forth in paragraphs 1–117 into their responses to each of the counts as if they were fully set forth therein.

119. Defendants deny the allegations contained in sentence one of Paragraph 119 of the FAC. Sentence two of Paragraph 119 of the FAC purports to quote from, characterize, or describe a statutory and regulatory regime, the underlying statutes and regulations of which are the best record of its contents. To the extent any further response is required, Defendants deny the allegations contained in sentence two of Paragraph 119 of the FAC to the extent they are inconsistent with the underlying statutes or regulations. Defendants deny the allegations contained in sentence three of Paragraph 119 of the FAC.

120. Sentence one of Paragraph 120 of the FAC purports to quote from, characterize, or describe a statutory and regulatory regime, the underlying statutes

and regulations of which are the best record of its contents. To the extent any further response is required, Defendants deny the allegations contained in sentence one of Paragraph 120 of the FAC to the extent they are inconsistent with the underlying statutes or regulations. Defendants deny the allegations contained in sentence two of Paragraph 120 of the FAC.

121. Paragraph 121 of the FAC asserts legal conclusions to which no response is required. To the extent that any further response is required, Defendants deny the allegations contained in Paragraph 121 of the FAC.

122. Paragraph 122 of the FAC asserts legal conclusions to which no response is required. To the extent that any further response is required, Defendants deny the allegations contained in Paragraph 122 of the FAC.

123. Paragraph 123 of the FAC asserts legal conclusions to which no response is required. To the extent that any further response is required, Defendants deny the allegations contained in Paragraph 123 of the FAC.

124. Paragraph 124 of the FAC asserts legal conclusions to which no response is required. To the extent that any further response is required, Defendants deny the allegations contained in Paragraph 124 of the FAC.

125. Defendants deny that the Relator and the United States are entitled to any of the relief requested.

ALL ALLEGATIONS NOT SPECIFICALLY ADDRESSED ABOVE ARE HERE AND NOW DENIED. Without limiting the foregoing, to the extent that any heading or footnote in the FAC is deemed to contain a factual allegation not specifically addressed above, any such allegations are denied.

Defendants further request that they be allowed to file an Amended Answer at the close of all discovery, if necessary or appropriate.

AFFIRMATIVE DEFENSES

Defendants assert the following affirmative defenses. Defendants undertake the burden of proof as to only those defenses deemed affirmative defenses by law, regardless of how such defenses are denominated herein. Further, Defendants reserve the right to amend this Answer if additional defenses, counterclaims, or third party claims become apparent through the course of this action. Further, Defendants reserve the right to assert any and all defenses on which Defendants do not bear the burden of proof, including but not limited to the defenses that Relator's claims are barred by the Court's Opinions and Orders dated December 30, 2013 and September 25, 2014 and that Relator has failed to allege facts or a cause of action sufficient to support a claim for attorney's fees and costs, or treble damages.

First Affirmative Defense

Relator fails to state a claim upon which relief may be granted.

Second Affirmative Defense

Relator's claims are barred by the doctrines of unclean hands, inequitable conduct, and/or in pari delicto.

Third Affirmative Defense

Relator's claims are barred, in whole or in part, by the doctrines of res judicata and collateral estoppel.

Fourth Affirmative Defense

Relator's claims are barred in whole or in part, as a result of set-off of monies previously paid by Defendants.

Fifth Affirmative Defense

Relator's claims are barred, in whole or in part, by government knowledge and/or the doctrines of laches, waiver, and/or estoppel.

Sixth Affirmative Defense

Relator's claims are barred, in whole or in part, by the public-disclosure bar in the False Claims Act, 31 U.S.C. § 3730(e)(4).

Seventh Affirmative Defense

Relator's claims are barred, in whole or in part, by the applicable statute of limitations. The FAC does not identify the date on which any claim was allegedly submitted. To the extent Relator attempts to assert claims based on claims

submitted beyond the applicable statutes of limitations, Relator's claims are barred, in whole or in part, by the applicable statute of limitations.

Eighth Affirmative Defense

To the extent Relator seeks equitable relief against Defendants, he is not entitled to that relief because he has an adequate remedy at law.

Ninth Affirmative Defense

Relator's claims are barred, in whole or in part, by the statutory exceptions provided for in 42 U.S.C. § 1320a-7b(b)(3).

Tenth Affirmative Defense

Relator's claims are barred, in whole or in part, by the regulatory exceptions provided for in 42 C.F.R. § 1001.952.

Eleventh Affirmative Defense

Relator's claims are barred, in whole or in part, to the extent that they have been released, settled, resolved through an accord and satisfaction, waived, or otherwise compromised.

Twelfth Affirmative Defense

Relator's claims are barred, in whole or in part, to the extent that the statutes he seeks to enforce, or the damages and penalties she seeks to recover, violate Defendants' constitutional rights or any other constitutional provision.

Thirteenth Affirmative Defense

Relator's claims are barred, in whole or in part, to the extent Defendants' alleged conduct is compelled by, authorized by, or otherwise consistent with, applicable statutes or regulations, including but not limited to N.J.S.A. 26:28-10.1.

Fourteenth Affirmative Defense

Defendants did not act knowingly within the meaning of the False Claims Act. Defendants did not have actual knowledge of any alleged falsity; act in deliberate ignorance of the truth or falsity of relevant information; or recklessly disregard the truth or falsity of relevant information. Defendants did not know that their conduct violated any law or regulation, including the Anti-Kickback Statute (which it did not); or act in deliberate ignorance or reckless disregard of the requirements of any law or regulation, including the Anti-Kickback Statute.

Fifteenth Affirmative Defense

The Government has ratified the alleged conduct of Defendants complained of in the FAC by failing to take any action despite its knowledge of the conduct.

Sixteenth Affirmative Defense

Relator's claims are barred, in whole or in part, because the Government had actual or constructive knowledge of the relevant facts and, therefore, Relator's claims are not false or knowingly false, and, alternatively, the Government was not defrauded.

Seventeenth Affirmative Defense

Relator's claims are barred, in whole or in part, by the original source bar in the False Claims Act.

Eighteenth Affirmative Defense

Relator's claims are barred, in whole or in part, because the Court lacks subject matter jurisdiction.

Nineteenth Affirmative Defense

Neither Relator nor the Government has suffered any injury, economic harm or loss, or damages, and neither is entitled to compensatory damages, civil penalties, interest, or other damages, penalties or awards.

Twentieth Affirmative Defense

Relator's asserted damages, if any, may have been caused by, or were the result of, actions or inactions of parties other than Defendants or parties over whom Defendants had no authority or control.

Twenty-First Affirmative Defense

Relator's asserted damages, if any, may have been proximately caused by independent, superseding, or intervening acts of parties or entities other than Defendants or parties or entities over whom Defendants had no authority or control.

Twenty-Second Affirmative Defense

Relator's claims for damages are barred by the due process clause of the Fifth Amendment of the United States Constitution and the excessive fines clause of the Eighth Amendment to the United States Constitution.

Twenty-Third Affirmative Defense

Relator's asserted damages may be barred, in whole or in part, because the alleged damages, if any, are too remote and/or speculative to allow recovery and/or because determining whether, or to what extent, Relator and/or the Government were damaged is impossible.

* * *

Defendants give notice that they intend to rely upon any additional defenses that are now or may become available or appear during, or as a result of, the discovery proceedings in this action. Defendants reserve their right to amend this Answer to assert those defenses. Defendants also state that, in this Answer, they have not raised defenses relating to allegations or claims that were dismissed pursuant to the Court's Opinions and Orders December 30, 2013 and September 25, 2014, and Defendants reserve the right to rely upon additional defenses in the event that such allegations or claims are allowed to be reasserted in this action.

PRAYER FOR RELIEF

WHEREFORE, Defendants pray for judgment as follows:

Judgment in favor of Defendants and against Relator, and the governments on whose behalf he makes claims, on all claims pled in Relator's complaint;

For such other and further relief as this Court deems just and proper, including, but not limited to, costs and reasonable attorneys' fees incurred by Defendants in defending this action.

DEMAND FOR JURY TRIAL

Defendants hereby demand a trial by jury on all issues so triable.

Respectfully submitted,

s/ James W. Christie
JAMES W. CHRISTIE
CHRISTIE PABARUE AND YOUNG
A Professional Corporation
1880 JFK Boulevard 10th Floor
Philadelphia, Pennsylvania 19103
(215) 587-1678
(215) 587-1699 (fax)

Enu Mainigi (*pro hac vice*)
Jennifer G. Wicht (*pro hac vice*)
WILLIAMS & CONNOLLY LLP
725 Twelfth Street, Northwest
Washington, District of Columbia 20005
(202) 434-5000
(202) 434-5029 (fax)

Attorneys for Defendants

Dated: November 21, 2014

CERTIFICATE OF SERVICE

I hereby certify that on November 21, 2014, a true and correct copy of Defendants' Answer and Demand for Jury Trial will be served upon parties who do not receive electronic service of the same from the Court via first-class mail, postage prepaid:

Marc M. Orlow, Esq.
Ross Begelman, Esq.
Begelman, Orlow & Melletz, Attorneys at Law
411 Route 70 East
Cherry Hill, NJ 08034

Charles Scott Graybow, Esq.
Office of the U.S. Attorney
District of New Jersey
970 Broad Street, Suite 700
Newark, NJ 07102

Geraldine D. Zidow, Esq.
Office of the New Jersey Attorney General
Medicaid Fraud Control Unit
25 Market Street
P.O. Box 085
Trenton, NJ 08625-0085

s/ James W. Christie
JAMES W. CHRISTIE